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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Optometry, Department of Health Professions
Virginia Administrative Code (VAC) citation	18 VAC 105-20
Regulation title	Regulations Governing the Practice of Optometry
Action title	Amendments to Chapter 20 to incorporate TPA certification Repeal of Chapter 30 – current TPA regulations
Document preparation date	8/25/04

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Preamble

The APA (Code of Virginia § 2.2-4011) states that an “emergency situation” is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.

- 1) Please explain why this is an “emergency situation” as described above.
- 2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

The adoption of an “emergency” regulation by the Board of Optometry is required to comply with amendments to §§ 54.1-3211 and 54.1-3223 and the second enactment clause in the passage of HB 856 by the 2004 General Assembly.

The second enactment clause of Chapter 744 of the 2004 Acts of the Assembly, which states “*That the Board of Optometry shall promulgate regulations to implement the provisions of this act to be*

effective within 280 days of its enactment,” requires the adoption of the regulation as an emergency in accordance with the Administrative Process Act, § 2.2-4011, which states that an “emergency situation” is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date. Chapter 744 was enacted on April 12, 2004, the day HB 856 was signed by the Governor.

The Board is amending Chapter 20, Regulations Governing the Practice of Optometry to incorporate the requirements for initial licensure with therapeutic pharmaceutical agents (TPA) certification, fees for applications and renewals, and the continuing education requirement for TPA-certified optometrists.

The Board is also repealing Chapter 30, Regulations on Certification of Optometrists to Use Therapeutic Pharmaceutical Agents.

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Optometry the authority to promulgate regulations to administer the regulatory system.

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

...

6. *To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...*

Chapter 744 mandates the promulgation of regulations for optometrists to be TPA certified:

<http://leg1.state.va.us/cgi-bin/legp504.exe?041+ful+CHAP0744>

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The purpose of the regulatory action is to implement provisions of Chapter 744 of the 2004 General Assembly, which requires that all persons newly licensed to practice optometry after June 30, 2004

must meet the qualifications for a TPA-certified optometrist. Therefore, the general regulations for the practice of optometry are being amended to incorporate the qualifications for TPA certification that are currently found in a separate chapter of the VAC. Since TPA qualification is now a prerequisite for licensure, the Board has amended examination requirements to allow entry into Virginia for optometrists who may have been TPA-qualified by an examination other than the NBOE examination including TMOD. The goal of the regulation is to maintain the standard for TPA certification but reduce the cost and allow for some flexibility in applying the requirements for evidence of minimal competency.

Substance

Please detail any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons why the regulation is essential to protect the health, safety, or welfare of Virginians. Delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

Amendments to Chapter 20 and repeal of Chapter 30: The “**current section numbers and requirements**” reference those found in Chapter 30.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
105-30-10	105-20-05	Sets out the definitions for “board,” “TPA,” and “TPA certification”	There is no change in the definitions, other than relocation to a new section in Chapter 20.
105-30-30	105-20-10 105-20-15	Sets out the requirements for an applicant to be licensed as an optometrist	These sections are amended in accordance with an amendment to § 54.1-3221, which specifies that everyone initially licensed as an optometrist after June 30, 2004 must meet the qualifications for a TPA-certified optometrist.
105-30-35 105-30-40	105-20-16	Sets out the education and examination requirements for TPA certification & specifies postgraduate training for someone who fails the TMOD examination 3 times	1) Requirements for completion of a graduate level training program approved by the board with a minimum of 20 hours of clinical supervision by an ophthalmologist are identical to current rules in Chapter 30 and consistent with provisions of § 54.1-3223. 2) Requires passage of the TMOD portion of the national examination or of another examination acceptable to the Board; or if TPA-certified in another state based on a state examination, requires the applicant to document that the exams were comparable. (TMOD is the standard by which the vast majority of optometrists are qualified to be TPA-certified. Presently, TMOD is one portion of the NBOE exam taken by all graduates of optometric schools and accepted in all states. There may be an occasionally applicant who has been TPA-certified in another state based on passage of

			<p><i>that state exam, so the Board wanted to be able to license that person if the exams were comparable. In addition, there is an examination in development that would replace the current examination and would have a different name, so the Board has provided that it may accept other examinations in order to be able to recognize any replacement for TMOD.)</i></p> <p>3) Current regulations require an applicant who fails the examination 3 times to repeat the portion of postgraduate educational program relating to TPA's. Optometric schools will no longer be offering separate & distinct TPA training, so it may be too burdensome to maintain the current rule. At the request of the Board, the optometry schools have fashioned remedial courses for applicants or optometrists who are the subject of a disciplinary action. Therefore, the Board has modified the current language to require an applicant who failed TMOD three times to complete additional postgraduate training as determined by the board (through a hearing before the Credentials Committee)</p>
<p>105-30-120</p>	<p>105-20-20</p>	<p>Sets the fees for applications, renewal, late renewal and other miscellaneous processes</p>	<p>Fees for TPA certification are incorporated into the fees for licensure and will result in a net reduction for practitioners.</p> <p>Application fee – Currently \$245 for optometric license and \$200 for TPA certification – <i>New fee is \$300 for both.</i></p> <p>A fee for endorsement of certification to use DPA's is being eliminated because current regulations require every optometrist, whether newly licensed by examination or endorsement, to be DPA-qualified. It is now part of the application process and not a separate endorsement.</p> <p>Annual licensure renewal without TPA certification – <i>unchanged at \$150</i></p> <p>Annual licensure renewal with TPA certification – Currently \$150 for license plus \$75 for TPA certification – <i>New fee is \$200 for both.</i></p> <p><i>Late renewal fees are approximately 1/3 of the annual renewal fee, consistent with the Principles for Fee Development.</i></p>
<p>105-30-90</p>	<p>105-20-70</p>	<p>Requires annual renewal of TPA certification and at least 2 of the CE hours be directly related to prescribing and administering TPA</p>	<p>Specifies that 2 hours of the current 16-hour requirement for optometrists with TPA certification be directly related to prescribing and administering TPA's.</p>

Repeal of Chapter 30: The “**current section numbers and requirements**” reference those found in Chapter 30, which is being repealed in this action.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
105-30-10		See above chart	Relocation to a new section in Chapter 20 (section 05).
105-30-20		Refers the Public Participation Guidelines in Chapter 10	Repealed; no similar amendment to Chapter 20 is necessary.
105-30-30		See above chart	Provisions in section 30 of Chapter 30 are included in amended sections 10 and 20 of Chapter 20.
105-30-35		See above chart	Provisions of sections 35 and 40 of Chapter 30 are now included in amended section 16 of Chapter 20.
105-30-40		See above chart	Provisions of sections 35 and 40 of Chapter 30 are now included in amended section 16 of Chapter 20.
105-30-60		Sets out the treatment guidelines and formulary of TPA's that may be used	Provisions of sections 60 and 70 are being amended and promulgated in Chapter 20 under an exemption from the APA but in accordance with specific requirements for recommendation from a TPA Formulary Committee, notification, public hearing, and publication of proposed and final regulations. These sections will become sections 46 and 47 within Chapter 20.
105-30-70		Sets out the treatment guidelines and formulary of TPA's that may be used	Provisions of sections 60 and 70 are being amended and promulgated in Chapter 20 under an exemption from the APA but in accordance with specific requirements for recommendation from a TPA Formulary Committee, notification, public hearing, and publication of proposed and final regulations. These sections will become sections 46 and 47 within Chapter 20.
105-30-90		See above chart	A requirement for 2 hours of continuing education related to prescribing and administration is incorporated into section 70 of Chapter 20. Renewal will be simultaneous with renewal of a license to practice optometry.
105-30-100		Sets out provisions for expiration of TPA certification and requirements for reinstatement	Requirements for renewal and reinstatement are provided in section 60 of Chapter 20 and are now being amended.
105-30-120		See above chart	Fees for TPA certification are incorporated into section 20 of Chapter 20.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.

There are no alternatives to the adoption of regulations, as it is mandated by the enactment clause of Chapter 744 of the 2004 Acts of the Assembly that amended regulations be in effect within 280 days of enactment, which was April 12, 2004. Through the emergency promulgation process, the Board is amending regulations stating educational and examination requirements for TPA certification and fees for applications and renewal.

Since § 54.1-3211 requires that after June 30, 2004, every person initially licensed to practice optometry must meet the qualifications of a TPA-certified optometrist, the Board considered amendments that would allow a person to meet the criteria for certification whether applying for licensure by examination or by endorsement. For those applying for initial licensure by examination, meeting the qualifications should not be an issue. Currently, approved optometric educational programs incorporate didactic and clinical training in TPA's, and the national examination incorporates a section (TMOD) to test minimal competency in the administration and prescribing of controlled substances.

For persons applying for licensure by endorsement, who may have been TPA-certified by a state examination, the current requirement for passage of TMOD may be problematic. The only option for such an applicant would be to retake the TMOD portion of the examination, since all newly licensed optometrists have to be TPA qualified. In its amended regulations, the Board has provided for those optometrists seeking licensure by endorsement, if the state examination was comparable to the TMOD portion of the national board examination. That determination would likely be made by a special conference committee that would review information provided by the candidate and the jurisdiction in which the optometrist took the examination.

As noted in the chart above, the Board has modified the current requirement for additional postgraduate training that meets the requirements for initial certification. Optometric schools will no longer be offering separate & distinct TPA training, so it may be too burdensome to maintain the current rule. At the request of the Board, the optometry schools have fashioned remedial courses for applicants or optometrists who are the subject of a disciplinary action. Therefore, the Board has modified the current language to require an applicant who failed the required examination three times to complete additional postgraduate training as determined by the board (through a hearing before the Credentials Committee).

The amended regulations will also result in a cost savings to those applying for licensure and optometrists who are currently licensed with TPA certification. For applicants, there will be a net reduction of \$145; for current licensees with TPA, annual renewal will be reduced by \$25. The Board is operating well within the revenue being produced, so it does not believe the reduction in fees will be problematic or necessitate a future fee increase.

Regulations stating the treatment guidelines and the TPA formulary are not being amended in the emergency action but will be promulgated under an exemption in § 54.1-3223. After the required notification and public hearing, the Board will adopt final regulations, which will become effective at the same time the emergency regulations are effective and Chapter 30 is repealed.

Please assess the impact of the emergency regulatory action on the institution of the family and family stability.

There is no impact of the emergency regulatory action on the institution of the family and family stability.